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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/505,305

10/27/2004

Lionel Breton

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29157 7590 12/24/2008  
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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

NOTIFICATION DATE

DELIVERY MODE

12/24/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/505,305	<b>Applicant(s)</b> BRETON ET AL.	
	<b>Examiner</b> Irene Marx	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 11-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 25-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The amendment filed 10/23/08 is acknowledged.

Claims 1-10 and 25-30 are being examined to the extent that they are directed to a bacterial culture only.

Claims 11-24 are withdrawn from consideration.

### ***Claim Rejections - 35 USC § 103***

Claims 1-10 and 25-30 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cavaliere Vesely *et al.* (EP 1020123) taken with Shields, Jr. *et al.* (U.S. Patent 6,156,355), Runge *et al.* (U.S. Patent No. 7,037,708), Berggren *et al.* (WO/00/79072) and Brassart *et al.* (U.S. Patent No. 5,603,930) and further taken with Reddy (U.S. Patent No. 4,806,368).

The claims are directed to an orally administrable composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid in some amount included in an ingestible carrier and including yeast extract.

As discussed in previous Office actions, the cited references disclose an orally administrable composition including a food or drink composition comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium and at least one carotenoid, included in an ingestible carrier.

The references differ from the claimed invention in that the specific strains of claim 4 are not disclosed and in the provision of milk products, milk based fermented products such as yogurt.. However, Brassart *et al.* adequately demonstrates that at least strains CNCM I-1225 and CNCM I-1226 are old and well known in the art as probiotics. In addition the reference demonstrates that the composition is provided as a yogurt a milk-based fermented product. See, e.g., col. 3, lines 55-60.

With regard to the pharmaceutical carrier, it is noted that the product of Berggren is provided at least in tablet form. In addition, yogurt containing strain CNCM I-1225 comprises a pharmaceutical carrier.

Regarding the presence of yeast extract, it is noted that Reddy adequately demonstrates that *Lactobacillus* and *Bifidobacterium* compositions containing yeast extract are old and well

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known in the art. See, e.g., Col. 3, Table. The reference discloses the benefits of the yeast extracts components to the viability of the bacteria, for example as a source of B vitamins.

The concentrations discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of concentrations for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the products of Cavaliere Vesely *et al.*, Shields, Jr. *et al.*, Runge *et al.* and Berggren *et al.* by providing a composition comprising a photoprotective amount of probiotic strains CNCM I-1225 and CNCM I-1226 as suggested by the teachings of Brassart *et al.* for the expected benefit of providing a healthful composition comprising a probiotic strain known to have favorable effects against disease and carotenoids such as  $\beta$ -carotene known to have at least antioxidant effects.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicant's arguments and Bureau-Franz Declaration have been fully considered but they are not deemed to be persuasive.

The declarant states at 4. that the invention is directed, in part, to an oral composition that includes an admixture of very specific constituents and alleges synergistic effects therefor. However, claim 1 is directed to

"An orally administrable composition for the photoprotection of the skin comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and at least one carotenoid wherein the at least one carotenoid is present in the composition in an amount from  $10^{-12}\%$  to 20% by weight, included in an orally acceptable carrier, the composition further comprising a yeast extract".

There is nothing specific about the constituents of this composition. The invention as claimed in the independent claim is directed very broadly to any probiotic lactic acid bacterium and is directed to various species thereof in claim 3. Only in claim 4 are specific strains claim

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designated, of which at least two strains are known in the art as shown by Brassart. In addition, the invention as claimed encompasses unidentified carotenoids at a level of between  $10^{-12}\%$  to 20% by weight. The nature of the carotenoids and the amount of  $10^{-12}\%$  are not addressed in the declaration and cannot be considered to be "specific". Moreover the compositions comprises an unidentified amount of yeast extract from unidentified yeasts.

The declaration shows favorable results for a composition comprising "matrix + La1  $10^8$  live + UV and this is designated "composition according to the invention". In section 8. it is stated that

"Depending on the group being tested, the mice were fed a variety of formulas of food including a food with no additional supplements; a food with maltodextrin; a "matrix" food having beta-carotene, lycopene, inactivated yeast extract and excipients such as, for example, magnesium stearate, corn starch, and silicon dioxide; a food with carotenoids; and the "matrix" food that was also supplemented with a bacteria (La1). The formulas for the treatments are set forth in Table 1 of Exhibit B."

There is no clear nexus or correlation between the invention as claimed and the results provided. There is no clear nexus or correlation between the  $10^8$  live La1 of the declaration and the invention as claimed directed to any probiotic lactic acid bacterium, the various species of claim 3 and even the specific strains of claim 4, which do not appear to include any amount of live "La1", which is not identified with any specificity. In addition, the declaration does not specify the level of carotenoids between  $10^{-12}\%$  to 20% by weight in the composition or the amount of yeast extract. It is also noted that claim 5 specifically recites "semi-active" or deactivated" lactic acid bacteria as opposed to "live" as in the declaration.

The Declaration does not clearly distinguish over the art and is not probative of unexpected results since it is not commensurate in scope with the claims. The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

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In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In *re* Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In *re* Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the *Cavaliere Vesely et al.*, *Shields, Jr. et al.*, *Runge et al.*, *Berggren et al.* are all directed to compositions comprising lactic acid probiotics and carotenoid or carotenoid derivatives even though references do not teach that the composition can be used for photoprotection of the skin. However, the intended use of the composition does not distinguish the composition since such undisclosed use is inherent in the cited compositions. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art compositions. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). When applicant claims a "composition in terms of function . . . and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection" (MPEP 2112). In this regard, it is noteworthy that the claims are directed to a composition comprising "10<sup>-12</sup>% to 20% by weight of an unidentified carotenoid.. There is nothing on the record to indicate to what extent a composition comprising carotenoids at the lower end of the range recited will have the required effect.

As noted previously the addition of yeast extract to probiotic lactic acid compositions is well known in the art for its viability enhancement.

In response to the arguments at page 5, paragraph 3 that the showing of the Affidavit is commensurate with the scope of the claims, it is noted that the use of the strain *Lactobacillus johnsonii* La1 is not clearly claim designated. Moreover, neither the data in the declaration nor the claim designated invention clearly designate the amount and nature of the carotenoids required or the nature or amount of yeast extract provided. Therefore, the Affidavit fails to demonstrate the unexpected photoprotective qualities of the composition **as claimed**.

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Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/  
Primary Examiner  
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